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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YOUNG, SHAWQUIA	

ART UNIT	PAPER NUMBER
1626	

NOTIFICATION DATE	DELIVERY MODE
12/04/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/552,082	PAIRAUDEAU ET AL.	
	Examiner	Art Unit	
	SHAWQUIA YOUNG	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8,12-14 and 16-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-4,6-8,13,14 and 16-19* is/are allowed.

6)☒ Claim(s) *12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/9/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4, 6-8, 12-14 and 16-19 are currently pending in the instant application. Applicants have cancelled claims 10 and 11 and added new claim 19 in an amendment filed on September 9, 2008.

I. *Response to Arguments*

Applicants' amendment, filed on September 9, 2008, has overcome the rejection of claims 11 and 12 under 35 USC 112, first paragraph for not being enabled for a solvate of the instant compounds. The above rejection has been withdrawn.

Applicants' arguments have not overcome the rejection of claim 12 under 35 USC 112, first paragraph for not being enabled for a method for treating asthma or rhinitis. Applicants argue that the specification teaches a genus of phenoxyacetic acid compounds that are capable of modulating CRTh2 receptor activity. Applicants further state that the specification teaches one how to both synthesize and administer the claimed compounds. The specification also provides an art recognized in vitro assay that can be used to evaluate the claimed compounds' ability to inhibit CRTh2 receptor activity. The CRTh2 receptor, ligands for this receptor, as well as the aforementioned inhibitory assay were known in the art as of Applicants' filing date. However, the Examiner wants to point out that Applicants have included prophylactic in the term "treatment" which embraces prevention. Applicants have not addressed this issue in the arguments filed on September 9, 2008. Applicants have not provided in the specification that the instant claims can prevent asthma or rhinitis since it is well known

in the art that for example, there is no cure for asthma. Therefore, since Applicants have included prophylactic in the term "treatment", the specification is not enabled for a method of treating asthma or rhinitis. The rejection is maintained.

II. *Information Disclosure Statement*

The information disclosure statement (IDS) submitted on September 9, 2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

III. *Rejection(s)*

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a

disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue".

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case,

The nature of the invention

The nature of the invention of claim 12 is a method of treating asthma or rhinitis. Support for the intended use of the instant compounds for ligand binding assay at PGD_2 is found on pages 30-31 of the specification.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease by what mechanism).

There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is the more specific enablement is necessary in order to satisfy the statute.

Applicants have included "prophylactic" in the definition of "treatment" on page 11 of the specification. The "prophylactic" embraces prevention and Applicants have not provided support for preventing any diseases mentioned in the specification.

Applicants are claiming a method of treating asthma or rhinitis.

Applicants' claims are therefore drawn to a method of treating or preventing asthma. Asthma is caused by inflammation in the airways. When an asthma attack occurs, the muscles surrounding the airways become tight and the lining of the air passages swell. This reduces the amount of air that can pass by and can lead to wheezing sounds. Asthma symptoms can be triggered by breathing in allergy-causing substances called allergens or triggers. Triggers include pet dander, dust mites, cockroach allergents, molds pollens. Asthma symptoms can also be triggered by respiratory infections, exercise, cold air, tobacco smoke, etc. Treatment is aimed at avoiding known allergens and respiratory irritants and controlling symptoms and airway

inflammation through medication. There are two basic kinds of medication for the treatment of asthma. Long-term control medications are used on a regular basis to prevent attacks, not for the treatment during an attack. Types include inhaled steroids, leukotriene inhibitors, Anti-IgE therapy, long-acting bronchodilators, cromolyn sodium or nedocromil sodium, aminophylline or theophylline. Quick relief medications are used to relieve symptoms during an attack. These include: short-acting bronchodilators (inhalers) and corticosteroids. There is no cure for asthma, though symptoms sometimes decrease over time.

Applicants' claims are therefore drawn to a method of treating or preventing rhinitis. Rhinitis is a nonspecific term that covers nasal congestion due to infections, allergies and other disorders. In rhinitis, the mucous membranes of the nose become infected or irritated, producing a discharge, congestion and swelling of the tissues. The most widespread form of infectious rhinitis is the common cold. Colds can be caused by as many as 200 different viruses which are transmitted by sneezing and coughing, contact with soiled tissues or handkerchiefs or by close contact with an infected person. Allergies are another frequent cause of rhinitis which is called allergic rhinitis. There is no cure for the common cold; treatment is given for symptom relief. Medications include decongestants to relieve stuffiness or runny nose. Allergies are treated with anti-histamines. Allergies may resolve or may be lifelong. There is no vaccine effective against colds. Prevention depends on washing hands often, minimizing contact with infected person and not sharing hand towels, eating utensils or water glasses. Allergies

may be prevented by avoiding the cause of the allergy, although this is not always possible or practical.

(URL: http://www.healthline.com/galecontent/rhinitis?print=true)

Hence, in the absence of a showing of correlation between all the diseases encompassed by the claims as capable of treatment by inhibiting PG2 one of skill in the art is unable to fully predict possible results from the administration of the compound of the claims due to the unpredictability of the role of inhibiting PG2 and, for example, since it is no known cure for asthma or rhinitis.

The amount of direction present and the presence or absence of working examples

The only direction or guidance present in the instant specification is the listing of several diseases applicant considers as treatable by the claimed invention found on pages 11-15. There are no working examples present for the prevention of any disease or disorder by inhibiting PG2.

Applicants have disclosed pharmacological data in a ligand binding assay for PGD2 on pages 30-31. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

The breadth of the claims

The breadth of the claims is drawn to a method of treating a disease mediated by prostaglandin D2, which comprises administering to a patient a therapeutically effective amount of a compound of formula (I), or a pharmaceutically acceptable salt as defined in claim 1. Claim 11 is drawn to a method of treating a respiratory disease in a patient suffering from, or at risk of, said disease, which comprises administering to the patient a therapeutically effective amount of a compound of formula (I) or a pharmaceutically acceptable salt or solvate thereof, as defined in claim 1.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what diseases out of all conditions such as cognitve disorders, hypertension, etc. would be benefited by the inhibition of PG2 would furthermore then have to determine which of the claimed compounds in the instant invention would provide treatment of the diseases.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* or *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

The specification fails to provide sufficient support of the broad definition of the term 'treatment" in a method of treating a disease mediated by prostaglandin D2. As a result necessitating one of skill to perform an exhaustive search for which diseases can be treated or prevented by what compounds of the invention in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

This rejection can be overcome, for example, by deleting the method claim.

IV. *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/

Examiner, Art Unit 1626

/Kamal A Saeed/

Primary Examiner, Art Unit 1626